IN THE

Supreme Court of the United States

October Term 1978

No. 78-605

THE UNITED STATES OF AMERICA, et al.,
Petitioners,

v.

GLEN L. RUTHERFORD, et al.,
Respondents.

BRIEF OF AMICUS CURIAE THE STATE OF CALIFORNIA IN SUPPORT OF PETITIONERS

~~BRIEF OF RESPONDENT IN OPPOSITION~~

GEORGE DEUKMEJIAN, Attorney General
ROBERT PHILIBOSIAN, Chief Assistant
Attorney General - Criminal Division
DANIEL J. KREMER,
Assistant Attorney General
HARLEY D. MAYFIELD,
Deputy Attorney General
ROBERT M. FOSTER,
Deputy Attorney General

110 West "A" Street, Suite 600
San Diego, California 92101
Telephone: (714) 237-7852

Attorneys for Amicus Curiae
State of California

INTERIM PRINTING & MAILING COMPANY
1105 WEST MORENA BOULEVARD, SAN DIEGO, CALIFORNIA 92110 — 275-3050

TOPICAL INDEX

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES
(Continued)

TABLE OF AUTHORITIES
(Continued)

TABLE OF AUTHORITIES
(Continued)

IN THE SUPREME COURT OF THE UNITED STATES

October Term 1978

No. 78-605

THE UNITED STATES OF AMERICA, ET AL.,
Petitioners,

v.

GLEN L. RUTHERFORD, ET AL.,
Respondents.

BRIEF OF AMICUS CURIAE THE STATE OF CALIFORNIA IN SUPPORT OF PETITIONERS

INTEREST OF AMICUS CURIAE

The Attorney General of California is the chief law officer of the state whose duty it is to see that the laws of California are uniformly and adequately enforced. (Cal. Const., art. V, § 13.)

Among these statutes is California Health and Safety Code section 1707.1 which prohibits anyone in California from selling, delivering, giving away or prescribing any drugs, medicine, compound or device for the diagnosis, treatment, alleveation or cure of cancer unless the item has received prior pre-market approval either under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) or by the State of California. In order to obtain approval for the item in question, the basic showing which must be made

according to rigorous scientific proof, is that the item is both safe and effective for the intended use. (Cal. Health & Saf. Code, § 1707.1, subds. (a) - (f); 21 U.S.C. § 355, subd. (d).)

Thus, legal and constitutional significance of the California statute is closely related to the federal statute under consideration in this case. The People of California thus have a vital interest in this Court's resolution of the constitutionality of federal statute 21 U.S.C. section 355 et seq. Therefore, the State of California respectfully submits this amicus curiae brief in support of petitioners, the United States of America, et al.

SUMMARY OF ARGUMENT

A requirement that a cancer remedy must first be shown to be both safe and efficacious before being allowed onto the commercial medical marketplace is a valid and necessary exercise of the government's police power. No constitutional right of privacy of a cancer patient is violated by such valid exercise of this police power. Moreover, since laetrile is a potentially dangerous drug, it is particularly appropriate as the subject of governmental premarket regulations.

ARGUMENT

I

PREMARKET REQUIREMENTS OF DEMONSTRABLE SAFETY AND EFFICACY FOR A DRUG IS A PROPER AND VITALLY NEEDED EXERCISE OF THE GOVERNMENT'S POLICE POWER

In repeatedly upholding attacks on premarket requirements of demonstrable safety and efficacy, this Court has made clear that such regulations are a proper and vitally needed exercise of the government's police power. (Weinberger v. Hynson, Westcott & Dunning (1973) 412 U.S. 609, 629-630; Ciba Corp. v. Weinberger (1973) 412 U.S. 640, 654.) Indeed, in interpreting the Federal Food, Drug and Cosmetic Act this Court specifically noted:

> "But Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labelled in mysterious scientific dress. The standard of 'well controlled investigations' particularized by the regulations is a protective measure designed to ferret out those drugs for which there is no affirmative, reliable evidence of effectiveness. The drug manufacturers have full and precise notice of the evidence they must present to sustain their NDA's [New Drug Applications], and under these circumstances we find FDA hearing regulations unexceptionable on any statutory or constitutional ground." (Weinberger v. Hynson, Westcott & Dunning, supra, at p. 622.)

Such food and drug laws are designed to protect "the public health and pocketbook against adulterated and misbranded drugs" and this objective "has led courts to declare with unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes." (United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos (D.Minn. 1944) 53 F.Supp. 746, 752, citing several decisions of this Court.)

Speaking of the Federal Food, Drug and Cosmetic Act of 1938, this Court observed in United States v. Dotterweich (1943) 320 U.S. 277, at page 280,

> "The purposes of this legislation . . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. . . ." (Id., emphasis added.)

The Dotterweich case was cited, quoted from and strongly reaffirmed in United States v. Park (1975) 421 U.S. 658, 668-669.) Thus, it is clear that the purpose of these types of premarket authorization as contained in the Food, Drug and Cosmetic Act is to protect consumers who are generally unable to protect themselves. (Kordel v. United States (1948) 335 U.S. 345, 349; Toole v. Richardson-Merrill Inc. (1967) 251 Cal.App.2d 689, 704.) As was stated in Hanson v. United States (D.C.Minn. 1976) 417 F.Supp. 30, 37,

> "The history of the Food, Drug and Cosmetic Act in the courts demonstrates that there is no shortage of peddlers who claim that their miracle drug must be made available to the consuming public without further delay. A parallel history of product liability litigation also demonstrates the danger that new drugs may be released without adequate testing, too often with tragic consequences. The balance between these competing considerations is one which has already been struck by Congress, and it is one which has been repeatedly upheld by the courts. . . ."

It is clear that either the federal government or a state government has broad powers "to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of the state's police power. The state's discretion in that field extends naturally to all professions concerned with health." (Barsky v. Board of Regents (1954) 347 U.S. 442, 449.) To justify the use of the police power on behalf of the public it must appear first that the interests of the public require such regulation and second that the means used are reasonably necessary for the accomplishment of the purpose. (Goldblatt v. Hempstead (1962) 369 U.S. 590, 594-595; Lawton v. Steele (1894) 152 U.S. 133, 137.) And, as noted by the California Supreme Court, "A police regulation for the protection of the public health will be sustained if, by any fair construction, it has a tendency to effect its object." (In re Gray (1929) 206 Cal. 497, 502.)

It has been held the interest of the public without question requires the state to regulate both the medical and drug field. "The right to exercise this power is so manifest in the interest of public health and welfare, that it is unnecessary to enter upon

a discussion of it beyond saying that it is too firmly established to be successfully called in question." (Minnesota ex rel. Whipple v. Martinson (1921) 256 U.S. 41, 45.)

Indeed the history of premarket approval requirements for drugs graphically demonstrates that there is a critical need for the government to require such showings of safety and efficacy. Moreover, the methods adopted in the federal statutes are reasonably necessary for the accomplishment of these important goals.

As noted in AMP Incorporated v. Gardner (2d Cir. 1968) 389 F.2d 825, cert. den. 383 U.S. 825, a major medical tragedy led to the passage of the Federal Food, Drug and Cosmetic Act of 1938 and the additions of the "new drug" and "prior approval" provisions. As late as August 1937, the bill was languishing in Congress.

> "The bill might well have been enacted without any prior approval sections had it not been for the 'Elixir Sulfanilamide' tragedy of September-October, 1937. [Fn. omitted.] As a direct consequence of that experience, involving the deaths of nearly one hundred persons across the nation who had consumed an untested drug preparation, bills supplementing [the original legislation] . . . were introduced . . . ." (Id., at p. 829.)

As was noted in a report to the Senate on this tragedy, "Most of the drug was administered on physician's prescriptions." (Sen. Doc. 124, 75th Cong., 2d Sess., Nov. 26, 1937.)

By 1962, the public's concern about the impact of drugs or treatments for disease which were not effective prompted President

Kennedy to recommend a hard line to Congress on drug frauds. President Kennedy expressed his concern in a message to Congress recommending strengthening of the existing food and drug laws which resulted in passage of the Drug Amendments of 1962:

> "The successful development of more than 9,000 new drugs in the last 25 years has saved countless lives and relieved millions of victims of acute and chronic illnesses. However, new drugs are being placed on the market with no requirement that there be either advance proof that they will be effective in treating the diseases and conditions for which they are recommended or the prompt reporting of adverse reactions. These new drugs present greater hazards as well as greater potential benefits than ever before -- for they are widely used, they are often very potent, and they are promoted by aggressive sales campaigns that may tend to overstate their merits and fail to indicate the risks involved in their use. For example, over 20 percent of the new drugs listed since 1956 in the publication "New and Non-Official Drugs" were found, upon being tested, to be incapable of sustaining one or more of their sponsor's claims regarding their therapeutic effect. There is no way of measuring the needless suffering, the money innocently squandered, and the protraction of illnesses resulting from the use of such ineffective drugs.
>
> "The physician and consumer should have the assurance, from an impartial scientific source, that any drug or therapeutic device on

the market today is safe and effective for its intended use; that it has the strength and quality represented; and that the accompanying promotional material tells the full story -- its bad effects as well as its good. They should be able to identify the drug by a simple, common name in order to avoid confusion and to enable the purchaser to buy the quality drugs he actually needs at the lowest competitive price.

"Existing law gives no such assurance to the consumer -- a fact highlighted by the thorough going investigation led by Senator Kefauver. It is time to give American men, women and children the same protection we have been giving hogs, sheep, and cattle since 1913, under an act forbidding the marketing of worthless serums and other drugs for the treatment of these animals."1/ (1962 U.S. Code Cong. & Admin. News, pp. 4143-4144, emphasis added.)

---

1. See Pharmaceutical Manufacturers Ass'n v. Richardson (D.C.Del. 1970) 318 F.Supp. 301, 307, in which the court cited witnesses before the hearings leading to the 1962 Drug Amendments corroborating President Kennedy's call for impartial judgment on drugs:

". . . 'a collection of impressions' will [not] furnish the truth, . . . 'this approach did not prevent doctors from having unbounded faith in the curative powers of leeches for hundreds of years before scientific evaluation became the preferred means of judging efficiency of therapy.'

The reasons why Congress followed President Kennedy's message and articulated precise and rigorous scientific standards for proof of compliance with or exemption from the provisions of the 1962 New Drug Amendments is explained in United States v. Articles of Food and Drug, Coli-Trol 80 Med. (D.C.Ga. 1974) 372 F.Supp. 915, 920-921:

"Quite properly, it is simply not enough to show that some people, even experts, have a belief in safety and effectiveness. [Fn. omitted.] A reasonable number of Americans will sincerely attest to the worth of almost any product or even idea. To remove the aberrations in uniformity which can result from a well-staged 'swearing match,' the law requires more. Indeed, it has been heretofore held that the purpose of the normal inquiry is not to determine safety and effectiveness at all, but to ascertain the drug's general reputation in the scientific community for such characteristics. United States v. 41 Cases, More or Less, 420 F.2d 1126 (5th Cir. 1970); AMP, Inc. v. Gardner, 389 F.2d 825 (2nd Cir. 1968), cert. den. 393 U.S. 825, 89 S.Ct. 86, 21 L.Ed.2d 95 (1968). It is certain that a conflicting reputation is insufficient to establish general recognition. United States v. An Article

---

1. (Continued)

. . . '[t]he magnitude of sales of a drug after vigorous promotion is no recommendation for its usefulness or efficacy'; . . ."

of Drug--Furestrol Vaginal Suppositories, 294 F.Supp. 1307 (N.S.Ga. 1968), aff'd 415 F.2d 390 (5th Cir. 1969).

"Therefore, what is required is more than belief, even by an expert; it is a general recognition based upon substantial scientific evidence as delineated in the regulatory guidelines. 21 CFR § 130.12. Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973). There is no reason to differentiate the holding in Hynson between human drugs and animal drugs. United States v. 14 cases--Naremco Medimatic, 374 F.Supp. 922 (W.D.Mo, Number 2806, January 29, 1974). Public health considerations are similar. Further, logic would dictate no lesser standard after-the-fact than in securing an application. Indeed, the reasoning of the Supreme Court appears to be that 'the reach of scientific inquiry' is the same whatever the forum. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645(b), 93 S.Ct. 2488, 37 L.Ed.2d 235 (1973)." (Emphasis added.)

The reasons behind a requirement that drugs used in the treatment of cancer be first determined safe and effective were most recently and strongly set forth in the opening remarks of Senator Edward Kennedy, Chairman, Senate Subcommittee on Health and Scientific Research of the Committee on Human Resources at hearings on July 12, 1977, before that Committee on "Evaluation of Information Which the FDA Based Its Decision to Ban the Drug Laetrile from Interstate Commerce," 95th Congress, 1st Session (hereinafter "Hearings"). His remarks are particularly

pertinent to the issues of constitutional protection posed to this Court since he views the laetrile issue not only as a legislator, but also as the father of a child who has cancer, who has committed his child to conventional cancer treatment and who has emerged with his child the apparent victor over his disease:

"There is no disease that the American people fear more than cancer. The very word terrifies many, and conjures up images of pain, suffering and terminal illness. Families fear it when it strikes a loved one because, in some cases, there is so little one can do. There is a feeling of hopelessness and helplessness and, of course, a feeling of guilt.

"I know these feelings first hand. I remember how I felt when the diagnosis was made on my son. What I remember about those first terrible days was the sense of outrage and of injustice that it had happened to him. I remember the search for the cure -- the answer that would save my son's life. I wanted to know every possibility. I wanted to see if there was a special treatment hidden somewhere in the vast array of medical resources available in the country.

"I know how very vulnerable people are in the circumstances -- how willing they are to grasp at any straw -- to try any approach -- to effect a cure.

"This is the time when people need the best information they can get; when they need to be able to

understand realistic alternatives. It is not a time when people are capable of sifting fact from fancy themselves.

"The emotions of the moment make a fully rational choice difficult enough and could tip the balance toward 'quick-fix' panaceas if they were presented as comparable alternatives to proven therapy.

"The role of the Food and Drug Administration in this tragic moment is to guarantee that the available drug therapies are the best and most effective that science can devise. Their role is to protect both the patient and his family from remedies that are neither safe nor effective. The elimination of useless treatments is a valid Federal role. It is a humanitarian role. It reduces the burden on cancer patients and their families and allows them to exercise their freedom of choice on the basis of informed judgments among viable alternatives.

"These issues are brought into dramatic focus by the subject of today's hearing -- Laetrile. Is it a useful addition to the armamentarium against cancer or is it a useless compound which has gained some acceptance because of the vulnerability of the people who decide to use it?

"We all have a high stake in the answers . . . ." (Hearings, at pp. 1-2, emphasis added.)

In dealing with a disease as serious as cancer, the need for prior demonstrations of safety and efficacy are particularly accute.

It is well recognized that the treatment of a life-threatening disease such as cancer with an ineffective drug is not sound medical practice because any delay in the institution of effective therapy allows the disease to progress unchecked until it may be beyond control. (Durovic v. Richardson (7th Cir. 1973) 479 F.2d 242.) As Justice Douglas stated in Ewing v. Mytinger & Casselberry (1950) 339 U.S. 594, 600:

> ". . . [Congress] may conclude, as it did here, that public damage may result even from harmless articles if they are allowed to be sold as panaceas for man's ills. . . ."

Indeed, this has been the repeated conclusion of the lower federal courts that have addressed the question. (United States v. General Research Laboratories (C.D.Cal. 1975) 397 F.Supp. 197, 199; United States v. Kordel (7th Cir. 1947) 164 F.2d 913, 917; see also Drown v. United States (9th Cir. 1952) 198 F.2d 999, 1006.)

Thus, given the goals and purposes underlying the premarket requirements of scientifically verifiable proof of both safety and efficacy, it is clear that such regulation is necessary and the means chosen by Congress to achieve that critically important goal are reasonably necessary for the accomplishment of the purpose.

II

ANY RIGHT OF PRIVACY WHICH HAS BEEN DEVELOPED IN RECENT YEARS BY THIS COURT DOES NOT STRETCH SO FAR AS TO ALLOW A PATIENT TO USE THE UNTESTED UNPROVEN DRUG OF HIS CHOICE

Although in recent years this Court has accorded constitutional protection to areas of private decision making in matters relating to family life, such as child rearing and education, procreation, contraceptives, marriage and abortion, none of these cases[2] support the "right" of a cancer patient to have access to the untested unproven remedy of his or her own choice.

Generally speaking the individual is protected by a zone of privacy which would give him the right to refuse all medical treatment. However, that zone may be entered by the state if there is a compelling state interest at stake. Thus, while an individual may have the right to decide that he will not, as a general matter, accept medical treatment, the state nonetheless can require compulsory small pox vaccination for the compelling state interest of protecting the public from epidemics. (See Jacobson v. Massachusetts (1905) 197 U.S. 11; Muhlenberg Hospital v. Patterson (1974) 320 A.2d 518; Prince v. Massachusetts, supra, 321 U.S. 158, 166-167.)

---

2. (Pierce v. Society of Sisters (1925) 268 U.S. 510; Meyer v. Nebraska (1923) 262 U.S. 390; Skinner v. Oklahoma (1942) 316 U.S. 535; Prince v. Massachusetts (1944) 321 U.S. 158; see, e.g., Griswold v. Connecticut (1965) 381 U.S. 479; Eisenstadt v. Baird (1972) 405 U.S. 438; Roe v. Wade (1973) 410 U.S. 113; Doe v. Bolton (1973) 410 U.S. 179.)

But where a patient has made the decision to seek medical treatment venturing into the commercial medical marketplace, he is subject to the valid state regulations of that marketplace. And state regulations in this area need only have a rational relationship to the goal sought to be achieved, i.e., a rational basis. A brief review of the major cases decided by this Court shows the underpinnings of this formulation.

In Griswold v. Connecticut, supra, 381 U.S. 479, the seminal case in this area, this Court struck down a Connecticut statute which prevented a doctor from prescribing to his patients contraceptive devices; devices which were recognized by the medical profession as both safe and effective. (Id., at pp. 481-486.) However, the court specifically noted it was not dealing with a statute that regulated the manufacture or sale of the item but rather the use of that item. Implicit in this discussion was the right of the state to require certain minimum safety and efficacy standards for medical items sold within its boundaries. (Id., at p. 485.)

Later, in Roe v. Wade, supra, 410 U.S. 113, this Court dealt not with the unfettered right of choice of treatment but only with the right of a woman to decide whether to terminate her pregnancy without unwarranted state interference. (Id., at p. 144.) But it must be noted that the Court went on to specifically uphold the right of the state to regulate the entire health care area in which the woman would seek her abortion. (Id., at pp. 163, 173.) Indeed, this Court specifically rejected an argument by some of the amici that an individual had an unlimited right to do with one's body as one pleased which could not in any way be regulated by the state. (Id., at p. 154.) Again, this Court made clear the right to privacy of

the individual did not curtail the more important right of the state to regulate the medical marketplace.

More recently in Whalen v. Roe (1977) 429 U.S. 589, this Court upheld a statute requiring that certain patient-identifying information be provided to the state whenever a physician prescribes a Schedule II drug; drugs in Schedule II (such as opium) have recognized medical uses but the highest potential for abuse among legitimate drugs. (Id., at pp. 592-593 and n. 8.) This Court did not attach constitutional privacy status to the decision to use Schedule II drugs (Id., at pp. 603-604), even though the disclosure requirements might result in patient reluctance to use such drugs when medically indicated. (Id., at p. 600.) This Court held that the disclosure requirements did not constitute ". . . an invasion of any right or liberty protected by the Fourteenth Amendment," (Id., at pp. 603-604, fn. omitted), and applied a "rational basis" test in sustaining the statute. (Id., at p. 598.)

Some of the appellants in Whalen were doctors who contended that the law impaired their right to practice medicine free of unwarranted state interference. The Court specifically rejected such a sweeping claim of privacy. "We have never carried the Fourth Amendment's interest in privacy as far as the . . . appellees would have us. We decline to do so now." (Id., at p. 604, fn. 32.)

Illustrative of the principle that the choice among medical alternatives in the medical marketplace is not itself a decision within the zone of constitutionally protected privacy is this Court's holding in Planned Parenthood of Missouri v. Danforth (1976) 428 U.S. 52. There, this Court struck down a state prohibition of a particular abortion procedure, saline amniocentesis. (Id., at p. 79.) However, the Court did not hold that

the prohibition violated any right to privacy. The Court also did not hold that because the right to privacy encompasses a woman's decision whether to have an abortion, the state therefore may not prohibit a particular abortion procedure. Rather, citing Roe v. Wade, supra, 410 U.S. at page 164, the Court stated the issue before it as follows: "[W]hether the flat prohibition of saline amniocentesis is a restriction which 'reasonably relates to the preservation and protection of maternal health.'" (Planned Parenthood of Missouri v. Danforth, supra, at p. 76, emphasis added.) The Court cited voluminous record evidence of the safety and effectiveness of saline amniocentesis, as compared with other available abortion procedures, and concluded that the state prohibition bore no reasonable relationship to protection of maternal health. (Id., at p. 76.) Significantly, in discussing the validity of the statutory prohibition of this particular medical procedure, the Court did not refer to any constitutional consideration of privacy. No such considerations were involved in the selection of that particular medical procedure by the patient and her physician. The procedure was evaluated by them and by the Court solely on the basis of medical evidence of its safety and effectiveness. (Id., at pp. 75-79.)

Planned Parenthood thus stands for the proposition that although the decision whether to have an abortion is within the constitutional zone of privacy, deserving the protection provided by the "compelling interest" standard, the selection of a particular abortion procedure is a medical matter, to which privacy status does not attach and which may be regulated by government, provided that a rational basis for such regulation exists.

In the instant case, the analogue of the right to decide whether to have an

abortion is the right to decide whether to receive or to forego cancer treatment or to attempt to prevent cancer by the use of drugs. But, although the decision whether to receive any treatment or to attempt to prevent cancer, may be constitutionally protected, the choice among treatment or preventive (if any existed) alternatives is not within the scope of the constitutional right to privacy. No constitutional right is abridged by making available to persons fearful of cancer and to cancer patients only those drugs which are proven safe and effective in cancer prevention or treatment and by precluding the sale or distribution of drugs which are ineffective in preventing or treating cancer.

As was set forth in argument I, supra, the premarket requirements of both safety and efficacy as embodied in 21 U.S.C. § 355 serve the critical need of protecting the public from unproven and thus harmful "remedies." The need for this form of government regulation is so important that it could easily satisfy the "compelling state interest" test used in dealing with fundamental rights. A fortiori, this regulation easily satisfies the rational basis test which properly applies when the state regulates the commercial medical marketplace.

III

RECENT EVENTS AND MEDICAL RESEARCH FURTHER SUPPORT THE FDA COMMISSIONER'S FINDINGS THAT LAETRILE IS NEITHER SAFE NOR EFFICACIOUS

After conducting extensive hearings to develop an administrative record on laetrile, FDA Commissioner Kennedy concluded that laetrile is not generally recognized by qualified experts

as a safe and effective cancer drug. Moreover, he noted that there is frank evidence of toxicity from the ingestion of the kernels or pits of apricots. (42 Fed.Reg. 39806 (Aug. 5, 1977).)

Since the date of those findings further evidence has developed to support his determination.3/ There is now evidence that laetrile may be mutagenic. (See Science (Nov. 11, 1977) vol. 198, pp. 625-626.) An important retrospective analysis is also now available. The National Cancer Institute undertook a study of individuals who had been using laetrile in this country. Letters were sent to 385,000 physicians and 70,000 other health professionals. Additionally, contact was made with organized pro-laetrile groups. Evaluation of the cases submitted revealed no statistical basis for concluding that laetrile has any anti-cancer activity. The full report of this analysis is reported in Special Report on Laetrile: The NCI Laetrile Review (Sept. 7, 1978) New England Journal of Medicine (vol. 299, no. 10), page 549 et seq.

Additional studies and reports on the inherent toxicity of laetrile when taken orally are also available. They are carefully noted in The Current Status of Laetrile (Sept. 1978) Annals of Internal Medicine (vol. 89, no. 3), page 389 et seq. The authors of the

---

3. It is of course true that the general rule of appellate review is that a decision by the court or an administrative agency should be evaluated upon the evidence before that entity at the time of its decision. However, in an area of continuing scientific investigation, such as laetrile, a court should always remain receptive to new scientific data which may have important ramifications on the legal issues under consideration. It is in this framework that amicus curiae presents the material in this argument.

report note, "With oral dosing, a toxic potential is manifest." (Id., at p. 391.) This point was recently brought home by the death of California resident Jo Anne Etta Pye. Mrs. Pye had a history of cancer of the breast but she refused to have any type of surgery or conventional therapy. Mrs. Pye turned to laetrile in oral form. On December 3, 1978, Mrs. Pye died as a result of cyanide intoxication from the laetrile. Moreover, the unchecked cancer had begun to spread through her body. (Amicus curiae respectfully requests that this Court take judicial notice of the records of the Alameda County Coroner, attached to the brief of amicus curiae, the American Cancer Society, as exhibit B. These records fully support the statements made in this argument.)

Mrs. Pye's death graphically illustrate the two fold danger in laetrile. Not only is there the danger from the nature of the drug itself, but also there is the danger of delaying those treatments already proven safe and effective, thereby allowing the disease to spread unchecked.

In United States v. Kordel, supra, 164 F.2d 913, 917, the court stated:

> "All were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of security in reliance on the drugs when they might need professional diagnosis and treatment for conditions which might respond to treatment if correctly diagnosed early enough, but which might become much more serious if not taken care of early. . . ."

Similarly, in a case involving the sale of a device by a chiropractor in violation of the Federal Food, Drug and Cosmetic

Act, the appellant argued that the instrument could not possibly harm anyone. The court responded that:

> "While the instruments may be harmless in themselves, their danger lies in the possibility that 'ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent.'" (Drown v. United States, supra, 198 F.2d 999, 1006, quoting United States v. Kordel, supra, 164 F.2d 913, 916.)

These events then make clear that laetrile poses two strong risks to the health of the population. Not only is laetrile itself hazardous but also by delaying conventional therapy it allows the cancer to proceed without any type of effective countermeasures. This two edged danger illustrates the terrible potential harm in allowing the "terminal cancer patient"[4] to have access to the drug. By allowing such access, that action communicates to other treatable cancer patients that there may be some value in laetrile. This would only serve to encourage them to abandon those forms of therapy already proven safe and effective and pursue unproven and unsafe alternate means. Thus, there is a tremendous potential harm to the population, by even allowing such so called terminal patients access to laetrile.

---

4. This of course assumes that it would somehow be possible to formulate adquate definitional terms to identify this group. As the FDA Commissioner's decision makes clear, such a classification scheme is probably impossible. (42 Fed.Reg. 39805 (Aug. 5, 1977).)

These recent events thus only serve to further support the original findings of FDA Commissioner Kennedy that laetrile was neither safe or efficacious. Moreover, there is conclusive evidence of the toxicity of laetrile. Given this potential for harm, the necessity for premarket approval is clearly the obligation of a government concerned with the welfare of its citizens.

CONCLUSION

For the reasons submitted above, amicus curiae, the State of California, respectfully submits that the premarket demonstrations of safety and efficacy as required by 21 U.S.C. § 355 is not only constitutionally proper but also realistically needed for the protection of the welfare of the citizens of the United States.

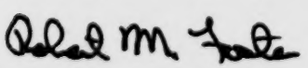
Respectfully submitted,

GEORGE DEUKMEJIAN, Attorney General

ROBERT PHILIBOSIAN, Chief Assistant
Attorney General--Criminal Division

DANIEL J. KREMER,
Assistant Attorney General

HARLEY D. MAYFIELD,
Deputy Attorney General



ROBERT M. FOSTER,
Deputy Attorney General

Attorneys for Amicus Curiae
State of California